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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,511	07/29/2003	John C. Jeppesen	6553-0501	6911

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RALPH D CHABOT
2310 E PONDEROSA DR
SUITE 4
CAMARILLO, CA 93010

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,511	JEPPESEN, JOHN C.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-21,23,25,28,29,31-36,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-21,23,25,28,29,31-36,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Examiner hereby acknowledges that Applicant has added new claims 40 and 41 in response the office action mailed on 1/24/06. Currently claims 18-31,23,25,28,29,31-36, and 39-41 are pending in the instant application.

Response to Amendment

The declaration filed on 6/23/06 under 37 CFR 1.132 has been considered but is ineffective to overcome the Katz US 2004/0115139 reference. Applicant allege that provisional application 60/418,986 does not disclose Examiner Bunin's basis for rejection because obtaining a three dimensional bite registration in a neutral centric position via TENS (see declaration page 2 lines 1-3). However, provisional application broadly discloses subject matter underlining TENS (see "this invention provides the sue of a neurotoxin to cause limited paralysis of the muscles of mastication in a patient" (declaration page 6, lines 1-5), use of neurotoxin renders TEN obvious; also see page 6, lines 7-9 for bite registration), therefore TENS disclosed in 2004/0115139 is also supported by 60/418,986.

Response to Arguments

Applicant's arguments with respect to claims 18-31,23,25,28,29, and 31-36 have been considered, but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18,19,33,35, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein US 6,012,455 in view of Manczur US 2,776,486

As to claim 18, Goldstein discloses a dual arch (fig.18, 130) oral appliance for obturating the oral cavity of the patient thereby substantially preventing mouth venting of PAP. Goldstein disclose the oral appliance further having an anterior, extra oral slide (fig.18, 132) affixed thereto positioning the oral appliance within a patient's upper and lower dental arches capable of maintaining the patient's mandible in a substantially neutral centric position without protrusion of the mandible. Goldstein has also disclosed a pair of PAP tubing (fig.18, 138,140) and connecting one distal end of each tube to an external source of positive airway pressure (Figure 15). In addition, Goldstein discloses a PAP tubing retention platform (fig.18, 136) mounted to the slide. The PAP tubing is also operatively connected to the PAP tubing retention platform. Goldstein has taught inserting the other end of each tubing into a respective nasal cavity for delivery of air from an external source as shown in Figure 15. The patient's nares are sealed with the nasal pillows (fig.18, 144,146). Goldstein lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as claimed. Thus, the method steps as cited in claims 18 would have been obvious result of using the apparatus of Goldstein. Goldstein further lacks the teaching of said dual arch oral appliance fabricated from dental impressions taken of the patient's upper and lower teeth and where said oral appliance is fabricated to maintain the patient's bit registration in the neutral centric position. However, Manczur teaches method of making a dental impression according to the claimed invention for providing a true and accurate centric occlusion (see col.1 lines 15-21).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method step of fabricating the impression as such to provide a true and accurate centric occlusion as taught by Manczur.

As for claim 19, Goldstein lacks the positioning of the PAP tubing retention platform 112 and the PAP tubing 118 anterioposteriorly to a position within a range of 5 mm to 30 mm from the labial surface of the maxillary anterior teeth. However, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein for positioning of the PAP tubing retention platform and the PAP tubing anterioposteriorly to a position within a range of 5 mm to 30 mm from the labial surface of the maxillary anterior teeth for a variety of users with different measurements based on age and facial structures. It is noted that applicant's specification does not set forth this range as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

As to claim 33, Goldstein discloses a dual arch oral appliance (130) for placement substantially within the oral cavity of a patient (Figure 15). Goldstein continues to disclose a retention platform (132) operably connected to the oral appliance for positioning anerioriallyof the patient's mouth (Figure 15). Goldstein also discloses a pair of air supply tubes (138/140) retained by the retention platform. Through the drawings, Goldstein teaches the dual arch oral appliance within a patient's oral cavity and engagement of one arch of the oral appliance to the patient's mandibular arch and the other arch of the oral appliance to the patient's maxillary arch

by the patient closing the oral cavity (see Figures 1,4,9, 11, 14, 19, and 20). Goldstein's device is capable of engagement without protrusion of the mandible and locating a neutral centric position with respect to the maxillary arch. Goldstein has continued to disclose positioning the end of each tube within a respective nostril, connecting the distal ends of each tube to an air supply source, and delivering an air flow to the patient from the air supply source through the pair of tubes as shown in Figure 14. The device of Goldstein is capable meeting the steps of supporting and stabilizing tubes connected to the dual arch (Figure 15). Goldstein lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as claimed. Thus, the method steps as cited in claims 33 would have been obvious result of using the apparatus of Goldstein. Goldstein further lacks the method step of dual arch oral appliance fabricated form dental impressions taken of the patient's upper and lower teeth and where said oral appliance is fabricated to maintain the patient's mandibular and maxillary arches in a neutral centric position and designed to substantially obturate the patient's oral cavity and prevent venting of air through the oral cavity. The teachings fabricating a dual arch and expected results of using a dual arch impression tray according to the claimed invention is a well-known method step used in dentistry in making a custom fit impression. Manczur teaches method of making a dental impression according to the claimed invention for providing a true and accurate centric occlusion (see col.1 lines 15-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method step of fabricating the impression as such to provide a true and accurate centric occlusion as taught by Manczur.

As to claims 35 and 39, Goldstein discloses connecting the tubes to the PAP tubing retention platform and sealing both patient's nares with each nare being sealed using the nasal pillow operably connected to a portion of the respective tubing positioned within a nostril (Figure 15). However, Goldstein doesn't teach the steps of selecting a PAP tubing retention platform appropriately sized for the patient's nasal features and/or width. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select a PAP tubing retention platform sized for a patient's nasal features or width since it was known in the art that such apparatus are manufactured to fit a variety of users with different measurements based on age and facial structures.

As to claims 40 and 41, Goldstein teaches the method step as applied for claim 33.

Claims 20, 21,23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein as modified by Manczur and in view of Landis et al. US 5,477,852.

As to claim 20, Goldstein lacks the PAP tubing retention platform as being composed of an acrylic material that is at least 3 mm thick. However, Landis teaches a similar Nasal PAP apparatus that is composed of an acrylic material (column 13, lines 61-66) that is at least 3 mm thick (column 12, line 39). Landis further teaches that it is well known in the art at the time of the invention to build PAP apparatus from acrylic and teaches the thickness used to be between 2 and 6 mm, which anticipate a 3 mm thickness. In addition, it is noted that applicant's specification does not set forth acrylic as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently

distinguish this claim over the prior art, barring a convincing showing of evidence to the contrary.

As to claims 21 and 23, Goldstein lacks wherein said acrylic material can be adjusted to optimize the desired angulations via application of heat of claim 21, and wherein said PAP tubing retention platform is created via injection molding of claim 23. However Landis teaches the acrylic material as being adjusted to optimize a desired angulation via application of heat (column 12, lines 41-47) (column 4, lines 40-42). Landis also teaches the PAP device as being created via injection molding (column 13, line 66). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Goldstein injection molded platform in order to maintain flexibility without breaking as taught by Landis.

As to claim 28, Goldstein discloses the anterior extra oral slide is bonded to the anterior surface of the oral appliance without the use of metal parts as shown in Figure 18, however, lacks the slide acrylically bonded to the oral appliance. It is noted that applicant's specification does not set forth acrylic bond as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish this claim over the prior art, barring a convincing showing of evidence to the contrary. Landis discloses a similar Nasal PAP apparatus that is composed of an acrylic material (column 13, lines 61-66). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Goldstein with the acrylic bond for maintaining a strong connection between the slide and an oral appliance.

Claims 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein as modified by Manczur and in view of Singer et al US 5,823,193.

As to claims 25 and 29, Goldstein lacks an obturator comprising an exterior surface made from acrylic material lined with an elastomeric material. However, Singer discloses a similar obturator for alleviating snoring. Singer discloses the obturator 10 comprising an exterior surface (32/34) made from an acrylic material lined with an elastomeric material (28/30,column 4, lines 20-29, see also abstract). Singer continues to disclose a hard exterior acrylic and deposited with an elastomeric material. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein with exterior acrylic material for protecting the teeth against grinding and an inner elastomeric material for conforming to the teeth and cushioning the jaw against impact forces.

Claims 31,32, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein as modified by Manczur and in view of Katz et al. US 2004/0115139.

As to claims 31 and 32, Goldstein lacks the oral appliance as being fabricated from a three-dimensional bite registration for orienting the position of the upper and lower dental arches. However, Katz teaches the aspect of fabricating an oral appliance such as a denture from a three-dimensional bite registration for orienting the position of the upper and lower dental arches (paragraphs 142-146). In addition, Katz teaches the bite registration as being produced utilizing Transcutaneous Electrical Nerve Stimulation (TENS) (paragraph 146, lines 6). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein so its made from a three-dimensional bite

registration via TENS as taught by Katz in order to achieve optimal dental function, stability, and harmony of the stomatognathic system.

As to claim 36, Goldstein lacks the step of obtaining a three-dimensional bite registration in a neutral centric position via Transcutaneous Electrical Nerve Stimulation (TENS). However, Katz teaches obtaining a three-dimensional bite registration in a neutral centric position via Transcutaneous Electrical Nerve Stimulation (TENS) (paragraphs 142-146) (especially paragraph 146, lines 6). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Goldstein so its made from a three-dimensional bite registration via TENS as taught by Katz in order to achieve optimal dental function, stability, and harmony of the stomatognathic system.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Diesso (US 7,101,178) and Tucker (US 2004/0096801) are cited to teach dual arch impression method.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/3/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

2/5/07